

EXAMINER INTERVIEW SUMMARY RECORD

In Paper Number 23, Examiner Pellegrino issued an Examiner Interview Summary Record regarding a telephonic interview of July 29, 2003. Applicants submit herein a statement of the substance of the interview. Examiner Pellegrino and Applicants' representatives Melissa L. Sistrunk and Thomas D. Paul discussed the Examiner's concerns that the claimed circular cross-section of the particle of the invention was not accurately reflected in the figures, of which FIG. 1 was the elected species for this prosecution. Applicants' representatives assured Examiner Pellegrino that the improper shading in the figures, which had been objected to in the Official Draftperson's Review dated February 12, 2003, would be removed to clarify that the arms indeed had circular cross-sections.

REMARKS

Claims 1-16, 20-22, 26, 64, 65, and 67-78 are pending in the application. New claims 79 and 80 are presented herein, and support for these claims comes from FIG. 1 and its description thereof. No new matter is entered herein.

Claim 70 is objected to under 37 C.F.R. §1.75(c) as being of improper dependent form for failing to further limit the subject matter of a previous claim. Through an inadvertent typographical error, claim 70 is dependent from itself. Accordingly, Applicants amend claim 70 herein. Applicants also amend claim 72 herein to reflect proper dependency.

Claims 1-4, 9, 10, 20-22, 26, 64, 67-70, and 73-78 are rejected under 35 U.S.C. § 102(b). Claims 1, 4-9, 11-16, 20, 21, 26, 64-65, 67, 69, 70, 71, 72 and 75-77 are rejected under 35 U.S.C. § 103(a).

I. Issues under 35 U.S.C. § 102(b)

Claims 1-4, 9, 10, 20-22, 26, 64, 67-70, and 73-78 are rejected under 35 U.S.C. § 102(b) for allegedly being anticipated by Sheppard *et al.* (WO 94/08912) ("Sheppard"). Applicants respectfully disagree.

The Examiner states that Sheppard teaches on page 2, lines 6-25, that spherical shaped or circular cross-section objects were known, and Sheppard disclosed that circular

cross-sectional particles have better densities. The Examiner interprets this statement to mean that Sheppard showed an understanding of packing particles with a circular cross-section in an array. The Examiner then extrapolates that because Sheppard *separately* teaches an array of particles with extremities, Sheppard “can be said” (Page 3, line 3 of the Office Action) to teach particles having extremities with circular cross-sections. The Examiner then refers to the MPEP § 2123 to support this weak reasoning by noting that prior art references are relevant for all they contain.

Applicants agree with the Examiner that prior art references are relevant for all they contain, however, such reference teaching should be read in light of the whole reference. Sheppard nowhere teaches an article with extremities having circular cross-sections. Although on Page 2, lines 6-25, of Sheppard provides background description discussing experiments regarding packing densities of spheres, and *spheres have no extremities*. This would only be relevant to the present invention if all of the extremities were removed and the center portion was left. Applicants assert that a ball-shaped article does not teach a toy jack-shaped article with extremities. Therefore, Sheppard cannot teach the claimed invention. Applicants arguments are not adverse to MPEP § 2123, describing *In re Heck*, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting *In re Lemelson*, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968). Sheppard may be relevant for all it contains, but it certainly does not contain or imply that the background description of spheres could be combined with the square cross-sectional extremities of FIGS. 2, 5, and 6 to provide a particle with extremities having circular cross-sections.

MPEP § 2123 also refers to Merck & Co. by stating that “a reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill in the art, including nonpreferred embodiments” (emphasis added). Applicants assert that no one in the art would read the background discussion regarding spheres and packing thereof and believe that the particle of Sheppard FIG. 2 and particles of Sheppard FIGS. 5 and 6 having extremities, planar-sided in nature, would have circular cross-sectional embodiments.

A claim is anticipated only if each and every element as set forth in the claims is found in the reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Thus, Applicants assert that Sheppard does not anticipate the claimed invention, and respectfully request removal of this rejection.

II. **Issues under 35 U.S.C. § 103(a)**

Claims 1, 4, 9, 20, 21, 26, 64, 67, 69, 70, and 75-77 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Black *et al.* (U.S. Patent No. 5,676,700) ("Black"). Claims 5, 6, and 11-13 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Sheppard in view of Chen *et al.* (U.S. Patent No. 6,180,606). Claims 5-8, 71, and 72 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Black in view of Barralet. Claims 14-16 are rejected 35 U.S.C. § 103(a) as allegedly being unpatentable over Black in view of Kondo. Claim 65 is rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Black. Applicants respectfully disagree with all rejections under 35 U.S.C. § 103(a).

The Examiner states on Page 6 of the Office Action that Applicants' arguments were not persuasive:

"A known or obvious particle does not become patentable simply because it has been described as somewhat inferior to some other product for the same use. In this instance and in response to the declaration of Mr. Cooper filed on 7/7/03, the arguments with respect to the Black patent are non-persuasive."

Applicants respectfully request clarification of this point. Mr. Cooper's declaration, our previous arguments, and even the specification itself state the functional advantage the circular cross-sectional design imparts to the particle over the oval cross-sectional design. Therefore, it is Applicants' assertion that our non-obvious particle is *superior* and not inferior.

A. *All Limitations Are Not Taught or Suggested*

To establish *prima facie* obviousness of a claimed invention, all of the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). By the Examiner's own admission ("... Black does not disclose the extremities have a circular cross-section."; Page 4 of the Action), Black lacks the teaching of the circular cross-section, and it also does not suggest a circular cross-section. Therefore, by definition there is no *prima facie* obviousness of the claimed invention.

There must be a teaching or suggestion to make the claimed limitations, and Applicants remind the Examiner that the level of skill in the art cannot be relied upon for suggestion. *Al-Site Corp. v. VSI Int'l Inc.*, 174 F.3d 1308, 50 USPQ2d 1161 (Fed. Cir. 1999).

Thus, Applicants assert that the Office has not established a *prima facie* case of obviousness to reject the claims under 35 U.S.C. §103. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438, (Fed. Cir. 1991).

B. *Circular- and Oval-Shaped Cross-Sections are not Interchangeable Designs and Impart Functional Differences*

The Examiner states that “it would have been an obvious matter of design choice to modify the oval or rounded cross-section of Black and make it circular, since *applicant has not disclosed that using a circular cross-section provides any advantage....*” This is incorrect. In the specification on Page 32, Applicants state:

“The circular cross-section of the extremities, or arms, of the shaped particle of the invention is beneficial for strength purposes, because an equivalent response to loading will occur regardless of the application of the load around the circumference. In contrast, an oval shape as is utilized in commercially available products and in U.S. Patent No. 5,676,700 has reduced resistance to loading when the loading is applied in the direction of the axis of the shorter width of the oval compared to the axis of the longer width of the oval.”

Moreover, this is addressed by Mr. Cooper in his declaration from Applicants previous filing of July 7, 2003. That is, on Page 3 of the Declaration:

“...the longer “side” of the oval contour can lie flat against the longer side of the oval contour of an adjacent particle for one pair of adjacent particles in an array, whereas the longer side of the oval contour of one particle can lie against the shorter “side” for another pair of adjacent particles in the same array. This configuration would thereby impart a somewhat unpredictable porosity for an array that is not palpable in function with an array from particles having circular cross-sections.”

Furthermore, he states on Page 3:

The design choice of the circular cross-section compared to the oval should not function in the same manner for their intended purpose, given their dissimilar contours. The circular cross-sectional area has proportionately the same forces in any direction across the cross-section, whereas in an oval cross-section the forces are not. For example, the forces across the different amounts of material (depending on the direction) of the cross-section in the oval-based arm provides weaker points in terms of tensile strength and so forth. The inherent functional differences mean that the design of the oval is not interchangeable with the design of the circle. The substitution of a circle for an oval cross-section is not a trivial substitution, and in the design of the particles of the present invention we have discovered that the circular cross-sectional properties are critical to how it functions. It would not be a mere design choice to exchange circle for oval.

The oval and circle cross-sections of the extremities are not transposable, as the Examiner's contention that a circle cross-section is an obvious matter of design choice. When there are limitations solely relating to ornamentation (having no mechanical function), these cannot be relied upon to patentably distinguish a claimed invention from the prior art. *In re Seid*, 161 F.2d 229, 73 USPQ 431 (CCPA 1947), but Applicants assert that the circular cross-section of the extremities is not mere ornamentation subject to whimsical design modifications. As stated in the specification on Page 32, Lines 3-9, the circular cross-section of the arms is beneficial for strength purposes, in contrast to an oval cross-sectional shape.

Even if the Examiner is to argue that the oval and circle configurations are functionally or mechanically equivalent, which they are not, the components are not necessarily obvious in view of one another. *Smith v. Hayashi*, 209 USPQ 754 (Bd. Of Pat. Inter. 1980).

Applicants submit that the particular configuration of the circular cross-section of the extremities of the particle is significant and provides certain functional advantages and characteristics that are not taught in the cited reference. Therefore, a modification to the Black particle to achieve the configuration of Applicants' claimed circular cross-section is not merely a matter of design choice. *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966).

C. Circle vs. Oval is Not a Matter of Design Choice

Applicants assert that the cross-sectional shape of the extremities of the particles are worthy of consideration to how they are designed; it is not obvious that such a small of a change can make a difference in the medical arts. The shape is of considerable importance and it is not obvious nor predictable to make one particular shape in light of another. As such, Applicants submit herewith third party references, all of which are submitted herewith in a Supplemental Information Disclosure Statement, illustrating the importance of design and the uncertainty in the art in which design configurations are useful. These references are discussed in detail in the accompanying affidavit under 37 CFR §1.132 by inventor Mike Cooper. Applicants remind the Examiner that references such as the accompanying affidavit and references discussed therein cannot be dismissed without an adequate explanation of why they would not overcome this rejection. *In re Alton*, 76 F.3d 1168, 1175, 1176, 37 USPQ2d 1578 (Fed. Cir. 1996).

In summary, though, it is clear from those of skill in the art that design shapes are so non-obvious and provide unpredictable enough results that they must be tested to determine those suitable for the purpose of facilitating or permitting sufficient bone ingrowth.

D. Black Fails to Provide a Method for Making the Particle

According to *In re Hoeksema*, 399 F.2d 269, 274-75, 158 USPQ 597, 601 (CCPA 1968):

If the prior art of record fails to disclose or render obvious a method for making a claimed compound, at the time the invention was made, it may not be legally concluded that the compound itself is in the possession of the public. In this context, we say that the absence of a known or obvious process for making the claimed compounds overcomes a presumption that the compounds are obvious, based on the close relationships between their structures and those of prior art compounds.

Also, *In re Hoeksema* states: [if] there is no showing of a known or obvious way to manufacture [the compound]....it seems to us that the "invention as a whole," which section 103 demands that we consider, is not obvious from the prior art of record.

Black fails to provide any process at all to manufacture the prior art particle; in fact, there are no Examples in this reference teaching how to make the particle. Moreover, the

accompanying affidavit by inventor Michael Cooper suggests that the particle is not sold in the market, likely because it can not be produced, and certainly not produced in mass quantities.

In the prosecution related to *In re Hoeksema*, an affidavit had been provided directed to the fact that the prior art reference did not disclose a process for producing the claimed compounds, and furthermore that there was no indication in the prior art reference that the fermentation process used to produce the prior art compounds could be used to produce appellant's compounds. In an analogous context, and as stated in the accompanying affidavit by inventor Michael Cooper, there is no indication how to produce Applicants' particles. The manufacture of Applicants' claimed particle was particularly difficult, and its success was the result of significant trial and error. In fact, the manufacture process for these particles is entitled, "MANUFACTURE OF BONE GRAFT SUBSTITUTES", and is the subject of U.S. Patent 6,630,153.

From the absence of sufficient teaching in Black for a manufacture method, there is certainly no teaching on how to generate Applicants' particles. In fact, and as also stated in the accompanying affidavit by inventor Michael Cooper, upon approaching outside vendors to manufacture Applicants' claimed invention, they were refused services on the basis of skepticism it could be manufactured. Therefore, Applicants assert that although there may be a similar relationship between the structure of Black and their own particle, in the spirit of *In re Hoeksema* there is no indication of *any* process to produce their particles in Black and that the absence of a sufficient process for making the particle overcomes a presumption that the compounds are obvious.

E. Black and Sheppard Teach Away from the Claimed Invention

Furthermore, Applicants assert that Black teaches away from the present invention, and therefore any combination of references with Black would also teach away from the present invention. Black teaches away from the circular transverse configuration by teaching the oval cross-section configuration. That is, Black clearly demonstrates the oval embodiment (col. 2, lines 57-67; FIG. 2; FIG. 7) and moreover states that at least in part that there are advantages of having an oval cross-sectional configuration (col. 3, lines 33-38), which would certainly steer another of skill in the art away from the circular cross-section,

establishing it is not an obvious matter of design choice as the Examiner suggested.

Applicants strongly assert that Black as a whole teaches away from the claims of the invention. Applicants respectfully remind the Examiner that a prior art reference must be considered in its entirety, *i.e.*, as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984). The oval cross-sectional shape of the Black structural elements and the indication that they are preferred and confer an advantage to the invention would, therefore, teach away from the circular cross-sectional configuration of the present invention. Thus, Applicants assert that Black teaches away from the present invention, indicating that the pending claims are, in fact, not obvious.

Thus, the improper rejection of Black indicates that any combinatory rejections with other references are also improper, and Applicants respectfully request their removal. If Black teaches away from the present invention in teaching a design choice that does not render Applicant's invention obvious, then the combination of references also teach away from the invention. Thus, regarding the rejection over Black in view of Chen, by the Examiner's own admission in the Office Action mailed February 20, 2003 on Page 2, Black fails to teach the claimed materials for the particles or composite materials. In addition, even adding Chen to Black does not provide or suggest the missing element in Black of circular cross-section. Applicants assert there is no suggestion or motivation for one of skill to combine Black and Chen to achieve Applicants' claimed invention, and Applicants respectfully request removal of this rejection.

Regarding the rejection over Black in view of Barralet, by the Examiner's own admission in the Office Action mailed February 20, 2003 on Page 3, Black fails to teach ceramic as gypsum or the array to have a porosity between about 40%-80%. Applicants assert there is no suggestion or motivation for one of skill to combine Black and Barralet to achieve Applicants' claimed invention. In addition, even adding Barralet to Black does not provide or suggest the missing element in Black of circular cross-section. Applicants respectfully request removal of this rejection.

Regarding the rejection over Black in view of Kondo, by the Examiner's own admission in the Office Action mailed February 20, 2003 on Page 3, Black fails to teach the

particle diameter being in the range of about 6mm. Applicants assert there is no suggestion or motivation for one of skill to combine Black and Kondo to achieve Applicants' claimed invention. In addition, even adding Kondo to Black does not provide or suggest the missing element in Black of circular cross-section. Applicants respectfully request removal of this rejection.

Regarding the rejection over Black in view of Sheppard, Applicants assert that in addition to Black teaching away from the invention Sheppard also teaches away from the present invention, and therefore the combination of these references could not be obvious. As acknowledged by the Examiner in a previous Action, Sheppard does not disclose a circular transverse cross-section configuration. In fact, Sheppard teaches away from the circular transverse configuration by teaching the square cross-section configuration. That is, Sheppard compares the advantages of a square cross-section over a circular cross-section, which would certainly steer another of skill in the art away from the circular cross-section, establishing it is not an obvious matter of design choice as the Examiner contends. On Page 12, L33-34, Sheppard states: "... (3) Plane-based coordination opportunities for aggregate that are an improvement on the point-to-point based coordination of spherical and random shapes..."

In addition to teaching away from the circular cross-section of Applicants' invention, the nature of Sheppard is a clear departure from the present invention, which would lead a skilled artisan in the field in a dissimilar direction. Applicants remind the Examiner about the previously filed Declaration Under 37 C.F.R. §1.132 of Dr. Ed Margerrison with the Response filed November 27, 2002.

Applicants reiterate that Sheppard adumbrates on Page 12, Lines 13-19 that there may be embodiments where the aggregates are not packed into a "zero matrix", but the majority of Sheppard does, in fact, teach that the design of the arms in Figures 5 and 6 is to increase the strength by nesting tightly and providing 0% void volume. Furthermore, the essence of the entire reference teaches that the purpose of the aggregate or array of particles as per Figures 5 and 6 is to increase the strength of a composite material with the array being surrounded by a matrix material.

Sheppard teaches that the composite is likely to have an increased strength and fracture toughness compared with other means of reinforcing composite structures. The array as shown in Figures 5 and 6 has essentially no open porosity within the structure, owing to the extremely highly reticulated structure that the "StarJack" shape gives. That is, it is mentioned that the arrangement described in Sheppard can often be achieved by mixing a number of those granules and applying vibration through *e.g.* mechanical or ultrasound means. With minimal vibrational forces, the particles of Sheppard regularly pack, and the circular cross-section of the particles of the present invention would not allow this. In fact, the advantage of the circular cross-section of the present invention is to reduce the potential for forming this reticulated structure so that a number of the individual granules together will retain an open interconnected porosity. The shape of the Sheppard granules described in the vast majority of the reference would, therefore, teach away from the configuration of the present invention.

For example, on Page 7, Line 1 Sheppard states, "One aspect of the present invention is an aggregate having a unique three-dimensional shape theoretically capable of packing to 100% density without any void volume....." The particles of the present invention cannot pack to 100% density, nor would such density be desirable for treating a bone deficiency (an element of Claim 1).

Also, on Page 12, Line 2 it states, "As shown by Figs. 4-6, this property permits the aggregates to be arranged in a nesting configuration, wherein faces of one aggregate are disposed adjacent faces of neighboring aggregates in a regular array.

Applicants expand the above citation of the following passage on Page 12 from Sheppard:

"We believe the Starjack, Tetratwin and Tetrastar represent novel classes of aggregate shapes with reticulate geometries marked by, for example:

- (1) The ability of same-class components of equivalent volume to nest uniformly;
- (2) Improved architectural properties of the nesting pattern itself (reticulate matrix), which may be varied in its thickness dimension in accordance with application demands;

(3) Plane-based coordination opportunities for aggregate that are an improvement on the point-to-point-based coordination of spherical and random shapes or the line-to-line based coordination of fibrous reinforcements;

(4) Substantially increased potential for crack path tortuosity....
(emphasis added)”

As described in the previously filed affidavit, Applicants assert that one skilled in the art would not recognize that the array of particles of the present invention illustrated in Figure 2 in the instant specification are in a “nested” array. Instead, one skilled in the art interprets the term “nested” to mean “to pack compactly together,” and in the context of the teachings of Sheppard for flat surfaces of the arms in a “plane-based coordination”, the packing would be so compact as to teach away from the bone deficiency-treating configuration of the array as taught by the Applicants.

Thus, Applicants reiterate that for multiple reasons Sheppard teaches away from the present invention. Therefore, the Black reference, the Sheppard reference and the combination of Sheppard with Black all teach away from Applicants’ invention, and this indicates that the pending claims are, in fact, not obvious in light of these references. Moreover, even adding Sheppard to Black does not provide or suggest the missing element in Black of circular cross-section.

F. An “Obvious to Try” Rejection is Being Applied

Applicants also submit that the rejections under 35 U.S.C. §103(a) for Black alone and in combination respectively with Chen, Barralet, Kondo, and Sheppard are each an application of an “obvious to try” standard in the field of shaped bone particles. For Black, the reference teaches a oval cross-sectional configuration and the advantages therewith, and although Applicants strongly assert this teaches away from the present invention, Applicants also suggest the Examiner is improperly citing an obviousness rejection wherein the rejection is more accurately an “obvious to try” rejection. The “obvious to try” standard has been held to constitute an improper ground for a 35 U.S.C. § 103 rejection. *In re O’Farrell*, 858, F.2d 894, 903 (Fed. Cir. 1988). An “obvious-to-try” situation exists when a general disclosure may pique an inventor’s curiosity, such that further investigation might be done as a result of the disclosure, but the disclosure itself does not contain a sufficient teaching of how to obtain the desired result or indicate that the claimed result would be obtained if certain directions

were pursued. *In re Eli Lilly & Co.*, 902 F.2d 943 (Fed. Cir. 1990). Similarly, Black does not teach Applicants invention, and although the Examiner alleges the particles in Black are obvious, Applicants assert the oval cross-sectional configuration of the particles teach away from the present invention, and the rejection is in fact an "obvious to try" rejection.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

Applicants believe no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 06-2375, under Order No. HO-P01952US1 from which the undersigned is authorized to draw.

Dated:

Nov. 24, 2003

Respectfully submitted,

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Attachments

APPENDIX

Attached herewith are replacement drawings.